

Application No.: 10/522,513
Filing Date: June 22, 2006

REMARKS

The withdrawal of previous grounds of rejection is gratefully acknowledged. Applicants submit claim amendments and arguments responsive to new grounds of rejection presented in the final Office Action. Applicants could not have presented these arguments earlier as the prior art rejections were set forth for the first time in the Final Office Action.

With this amendment, Claims 128-129, 131, and 134 have been amended. The claims have been amended to delete reference to HCV and BCV and to narrow the scope of the claimed immunogenic compositions to advance prosecution. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Claims 1-127, 130, 132-133, 137-143, and 145-163 were previously canceled.

New claims 166-167 depending from claim 134 are added which are directed to embodiments in which the coronavirus is inactivated (claim 166) or attenuated (claim 167) mirror previously presented claims 164-165 depending from claim 128. These claims do not raise any new issue as this issue has already been considered as indicated by the Final Office Action at page 4, paragraph 2). Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Restriction / rejoinder

Applicants respectfully acknowledge that claim 144 is withdrawn from consideration as it is directed to a nonelected invention. However, claim 144 is a process claim that depends from product claim 128 and includes all of the limitations thereof. With this amendment, claim 128 is believed to be in condition for allowance. Accordingly, Applicants believe that rejoinder is proper.

Rejoinder and allowance of claim 144 is respectfully requested.

Rejection under 35 U.S.C. § 102(b)

Claims 128, 129, 131, and 135 are rejected under 35 U.S.C. § 102(b) as being anticipated by Parker (U.S. Patent No. 5,672,350).

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In response to the rejection, claims 128 and 131 have been amended to recite “a coronavirus having a Spike (S) protein with at least ~~90%~~ 97% amino acid identity with Canine Respiratory Coronavirus (CRCV) S protein” (claim 128) or “with SEQ ID NO: 4” (claim 131). Support for the amendment is found at least in the original claims (see claims 95, 107, 113, 131, 140) and in the specification at page 10, line 13, for example. Reference to BCV and HCV has been deleted from claims. The E2 protein of Parker has 95.2% sequence identity. Accordingly, the E2 protein does not meet the limitations of the amended claims.

The Examiner also asserts that a fragment of the S protein of Parker, et al. from residues 1101 to 1363 has 97.7% identity to the corresponding region of SEQ ID NO: 4. In response, claim 131 has been amended to “an immunogenic fragment of SEQ ID NO: 4, wherein the fragment is at least 200 amino acids in length”. Claim 128 has been similarly amended.

In view of Applicants’ amendments, withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 128, 131, 134, 135, 164, and 165 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Knape, et al. (U.S. Patent No. 6,974,577) Genbank Accession No. AAF25499 (2000) and Hajer and Storz (Archives of Virology, 1979).

As discussed above, the present claims are amended so that the LY-138 protein of Genbank Accession No. AAF25499 is excluded from the claim scope.

As CRCV was unknown prior to the present application, there was no way for one of ordinary skill in the art to arrive at the claimed invention. Even starting from the LY-138 protein, the cited references provide no further guidance which would allow one of ordinary skill in the art to arrive at the claimed CRCV S Protein or a protein with 97% sequence identity to the CRCV S Protein (SEQ ID NO: 4). The Examiner states that “There would have been a reasonable expectation of success, given the knowledge that BCV LY-138 shares a high degree of homology with that of a CRCV S protein as taught by Genbank Accession No. AAF25499” (Office Action, page 5, paragraph 3) . However a comparison between the CRCV S protein and the BCV LY-138 protein is only possible in light of Applicants’ disclosure of SEQ ID NO: 4 from CRCV S protein, which was unknown prior to the present application. Furthermore, the prior art does not teach amino acids specific to CRCV S as set forth in claim 131. Starting with

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the BCV LY-138 and utilizing the disclosure of Knape, et al., one of ordinary skill in the art could not have achieved the presently claimed CRCV S compositions. Accordingly, the prior art does not provide sufficient guidance to obtain the presently claimed CRCV S immunogenic compositions from the LY-138 of Accession No. AAF25499.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 128, 131, 134-136, 164, and 165 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Knape, et al. (U.S. Patent No. 6,974,577) Genbank Accession No. AAF25499 (2000) and Hajer and Storz (Archives of Virology, 1979) and Acree, et al. (U.S. Patent No. 4,567,043).

The Examiner cites US 4,567,043 as teaching the use of canine adenovirus (CAV) and canine parainfluenzavirus (CPIV) along with a canine coronavirus in a caccine composition. The Examiner alleged that it would have been obvious to replace the canine coronavirus in U.S. 4,567,043 with BCV strain LY318.

As discussed above, the present claims are limited to a coronavirus having an S protein with at least 97% sequence identity to the CRCV S protein and to a fragment of at least 200 amino acids from the CRCV S protein. As discussed above, the combination of references does not lead to the claimed invention because CRCV was not known prior to Applicants' application. Accordingly, the combination of references provides insufficient guidance to arrive at the CRCV S protein from the LY-138 protein.

Regarding Acree, et al. the coronavirus disclosed by Acree, et al. is an enteric canine coronavirus (CCV), unrelated to the canine respiratory coronavirus (CRCV) of the present invention.

Although Acree, et al. do not teach the sequence of the enteric CCV strain, the S protein of another enteric CCV, strain 1-71, has only 21% amino acid sequence identity with the CRCV S protein sequence (see page 5, lines 8-11 of the present specification).

There was no motivation to replace the canine virus (CCV) in a canine vaccine with the disclosed bovine coronavirus (BCV) in light of the high level of sequence divergence between

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CCV and BCV. The Examiner states "There would have been a reasonable expectation of success, given the knowledge that BCV LY-138 shares a high degree of homology with that of a CRCV S protein as taught by Genbank Accession # AAF25499" (Office Action, page 6, last paragraph). However, this knowledge is only possible through Applicants' disclosure as the CRCV S protein was unknown prior to the present application and thus unavailable for comparison with other proteins. The knowledge that BCV LY-138 has homology with CRCV S was not in the prior art at the time of filing of the present application. Accordingly, one of ordinary skill in the art could not have achieved the presently claimed invention based upon the references taken as a whole.

In view of Applicants' amendments and arguments, withdrawal of the rejection is requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

The Examiner is referred to the listing provided with the response filed June 19, 2009.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the

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Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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